

Guidelines for Creating Pre-screening Questions

The CSSC Call Center understands that there are many nuances and criteria that make patients eligible or ineligible for your trials. Because our goal is to send you the most appropriate patients through a smooth and seamless referral process, we would like to capture as many of these nuances as we can.

We have devised a list of guidelines, or rules of thumb, that we hope will help you formulate an appropriate dedicated screening process for your protocol(s), as well as help us screen the most eligible candidates for your trials. These suggestions include:

- 1. When devising screening questions, please be as concise as possible.
- 2. Questions should be designed for yes or no (or 'don't know') answers and, based on the yes/no answer, allow you to easily decide whether to continue with the screening or consider the patient ineligible.
- 3. The number of questions may be as few as one or as many as you need.
- 4. As you develop your screening protocol, think of the following:
 - What would automatically rule a patient as ineligible for your study?
 - What is the minimum ECOG status your study will accept? An example of the question would be, "Do you have an ECOG of at least 2?" (Yes = eligible; No = ineligible)
 - Will you take patients with an autoimmune disease?
 - Will you accept patients on coumadin, oxygen, chemotherapy, or biologic treatment (e.g., if they've been on Taxol, will you accept them)?
 - What is the maximum number of regimens they may have received?
 - Will you accept a patient with brain metastasis? If yes, must there be a period of time since they last received treatment and should subsequent scans have shown stable disease?
 - Must patient be NED for enrollment?
 - Are you looking for a patient in CR?
 - Is it okay to have had treatment for metastatic disease, or are you looking for newly diagnosed cases?
 - What lab values can make a patient ineligible? (Keep in mind that many patients do not know current lab values, especially chemistries.) For example, "No patients with platelets less than 100K, no bilirubin greater than 2.0," etc.
 - Will you accept a patient in hospice?
 - Will you accept patients currently receiving treatment?

Again, the above list is meant as a guideline for you as you formulate questions. You may choose to use any or none of the examples on this list. We understand that each study is unique, as are its eligibility and ineligibility criteria. Your questions can be as detailed or broad as you want them to be.